Mr W. Reinert  
Chemicals, contaminants, pesticides  
DG SANCO  
European Commission  
B-1049 Brussels BELGIUM

Brussels, 17 November, 2010

EFSA Revision of lime sulphur and Azadirachtin

Dear Mr. Reinert,

We write to highlight the importance of two substances, currently being reviewed for inclusion in Annex I of EEC Directive 91/414, due to their essential requirement for use by European organic fruit, vegetable and wine producers.

We request that you take into consideration that the availability of these two products is of very high importance for organic fruit and vegetable production in Europe. I must emphasise that there is an essential need and use for these two products.

**Lime sulphur** is used for controlling fungal disease, especially in organic orchards and is of high importance for organic fruit production. If lime sulphur were not available to organic growers, significant reduction in crop yield would be expected. This is particularly relevant in years with heavy rainfall (such as 2010) where fungal diseases including apple scab (*Venturia inaequalis*) can develop to a level where they threaten economic viability. Under the European climatic conditions, lime sulphur is of vital importance for organic fruit growing. The substance furthermore plays an important role in the ongoing process to reduce the use of copper in organic fruit growing. The mandatory levels for the maximum use of copper based substances in organic fruit growing depend mainly on the continued availability of lime sulphur.

**Azadirachtin, an extract from the tropical Neem tree** (*Azadirachta indica*) has a very high importance for organic agriculture in the world, being one of the traditional active ingredients of highest reputation. A lot of scientific and practical work has been done in the countries of origin of this plant to establish programs for the use of these extracts for plant protection, especially in organic crops labelled for exportation to Europe. In European organic production Azadirachtin is essential for the control of several important pests for which no alternative products are available. For instance, it is the only known product for an effective control of the rosy apple aphid (*Dysaphis plantaginea*), one of the most dangerous key pests in organic fruit production.
Furthermore, Azadirachtin plays a very important role in resistance management in organic farming for several pests, e.g. the Colorado potato beetle (*Leptinotarsa decemlineata*). Neem extracts are registered in several European Member States as Germany, Italy, Spain, The Netherlands and Austria. Although the content of Azadirachtin may vary seasonally or regionally the technical extracts are standardised and analytically clearly defined especially with respect to all the limonoids so that a uniform composition can be guaranteed for all the extracts and formulations.

Additionally, we want to point out to that documented differences between products of natural vs. synthetic origin should be considered in the evaluation process. This has been considered in detail in a proposal of IBMA to DG SANCO and in SANCO 10472/2003 as well. The organic sector has previously made proposals for an adapted evaluation procedure appropriate to the types of products (including natural substances) permitted for use in the EU organic standards. For example, the EU 5th Framework ORGIN project (www.organicinputs.org) specifically made recommendations in this area.

In some cases it is necessary to adapt the evaluation process to the specific characteristics of the natural substances in question. For instance, standard requirements such as the use of radio-labeled metabolism studies for residue definition and risk assessment should be adapted to the specific characteristics of plant extracts, if it is necessary and possible. This general concept was also recognized by EFSA, as documented in a letter to IFOAM (Letter of EFSA to M. Schlüter, IFOAM EU of 6th Sept 2010).

The future availability of these two substances is of great importance for European organic production and it would help to secure the existence of farmers.

We remain available for any further discussion or inquiries.

Yours sincerely,

Marco Schlüter, Director IFOAM EU Group

cc: Ms Patrizia Pitton, Legislative officer, Chemicals, contaminants, pesticides, Mr. Jean-Francois Hulot, Head of unit, Organic Farming, DG AGRI,